Special 510(k) Summary
Line Extension to the OASYS® System

Proprietary Name:	Stryker Spine OASYS® System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II
	21 CFR 888.3070 (b)(1): Pedicle Screw Spinal System,
	21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis
Device Product Code:	87 MNI: Orthosis, Spinal, Pedicle Fixation
	87 KWP: Appliance, Fixation, Spinal Interlaminal
For Information contact:	Curtis Truesdale
	Regulatory Affairs Project Manager
	2 Pearl Court
	Allendale, NJ 07401
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Date Summary Prepared:	January 11, 2008

Predicate Device Identification Stryker Spine OASYS® System: K032394, K052317, K062853, K072568

Predicate Device Description

The Stryker Spine OASYS® System is comprised of rods, polyaxial screws, bone screws, hooks, connectors, and an occiput plate. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from Titanium alloy and CP Titanium and are provided non-sterile. The Stryker Spine OASYS® System can be linked to the Stryker Spine Xia® Spinal System, Xia 4.5 System and SR90D System via the rod-to-rod connectors.

Description of Device Modification

This Special 510(k) submission is intended to introduce a line extension to the predicate OASYS™ System, which consists of the addition of a cross connector plate and associated components (connector blocker and nut).

Intended Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the Stryker Spine OASYS® System is intended for: Degenerative Disc Disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Spondylolisthesis; Spinal Stenosis; Fracture/Dislocation; Atlanto/axial fracture with instability; Occipitocervical dislocation; Revision of previous cervical spine surgery; and Tumors.

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Stryker Spine Oasys® System can also be linked to the Xia System, Xia 4.5 System and SR90D System via the rod-to-rod connectors.

Statement of Technological Comparison:

Testing has demonstrated that the additional cross connector components have equivalent mechanical properties to the predicate OASYS® System (K032394). Both the new components and the existing system components are intended to address the same indications for use. Both the new components and the existing components are made from the same materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

Stryker Spine
% Mr. Curtis Truesdale
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, NJ 07401

Re: K080143
Trade/Device Name: OASYS System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: January 11, 2008
Received: January 22, 2008

Dear Mr. Truesdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080143

Device Name: _ Line Extension to the Stryker Spine OASYS® System

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput -T3), the Stryker Spine OASYS® System is intended for:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

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The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 -T3) spine.

The Stryker Spine OASYS® System can also be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carlene Purcell

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080143